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FILED
WILLIAMSPORT

MAR 19 2021

PER _____

DEPUTY CLERK

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,
Ex rel.
GERARD F. JACKSON

Plaintiff,

v.

CLARO SCIENTIFIC LABORATORIES,
INC., ROSSITER & CUMMARO
ENTERPRISE LLC, DOES 1-100,
and JOHN AND JANE DOES 1-100,

Defendants.

)
4: CV 21 - 497
CASE NO.:
JUDGE BRAUN

(FILED UNDER SEAL)

QUI TAM COMPLAINT

This is an action brought by Plaintiff/Relator Gerard F. Jackson ("Relator") on behalf of the United States of America pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729-3732 ("FCA"). In support thereof, Relator alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

1. Defendants, Claro Scientific Laboratories, Inc. ("Claro"), Rossiter & Cummaro Enterprise LLC ("R&C Ent"), Does 1-100, and John and Jane Does 1-100

(collectively “Defendants”), have engaged in actions designed to defraud the United States by knowingly submitting and/or causing to be submitted false and/or fraudulent claims for payment to the Medicare, Medicaid, and CHAMPUS/TRICARE (“Government Payors”) programs in violation of the federal False Claims Act, 31 U.S.C. § 3729 et seq.

2. Defendants have engaged in a scheme to defraud the United States by (1) fraudulently billing Government Payors for diagnostic tests and/or other medical services that were never performed, or were not ordered by the patient’s treating physician, (2) engaging in improper marketing practices which violate the Anti-Kickback Statute, and (3) engaged in improper practices involving telehealth physicians.

3. The FCA provides that any person who knowingly submits or causes to be submitted to the Government a false or fraudulent claim for payment or approval is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus three (3) times the amount of damages which the Government sustains because of the acts of the person. The FCA permits persons having information regarding a false or fraudulent claim against the government to bring an action on behalf of the government and to share in any recovery.

4. Pursuant to the FCA, Relator seeks to recover on behalf of the United States damages and civil penalties arising from Defendants’ intentional submission of false and fraudulent claims to government-funded healthcare programs (Government Payors).

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, 1345 and 1367.

6. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, because Defendants can be found in, reside in, transact business in, and/or have committed the alleged acts in the Middle District of Pennsylvania.

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)-(c) and 31 U.S.C. § 3732(a) because Defendants can be found in, reside in, have transacted business in and/or have committed the alleged acts in the Middle District of Pennsylvania.

8. Relator is an original source as defined by the FCA in 31 U.S.C. § 3730(e)(4)(B) because all of the allegations in this Complaint are based on evidence directly acquired by Relator independently and through his own efforts. None of the allegations set forth in this Complaint are based on public disclosure of information in a criminal, civil, or administrative hearing in a Congressional, administrative, or General Accounting Office report, hearing, audit or investigation, or from news media.

9. Relator made a voluntary disclosure to the United States prior to the filing of this lawsuit, as required by 31 U.S.C. § 3730(b)(2).

PARTIES

10. The United States is the real party in interest to this lawsuit.

11. Relator Gerard F. Jackson is a United States citizen currently residing in Centre County, Pennsylvania. He is a senior citizen who receives his medical health insurance through Medicare.

12. Defendant Claro Scientific Laboratories, Inc. is a for-profit corporation organized and existing under the laws of the state of Delaware with a registered agent of The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801 and an advertised business address of 1408 Horizon Ave, Suite 101, Lafayette, Colorado 80026.

13. Defendant Rossiter & Cummaro Enterprise LLC, is a for-profit limited liability company organized and existing under the laws of the state of Wyoming with a registered agent of Stephen Rossiter, 4501 Nesmith Rd, Plant City, Florida 33567 and a registered principal office of 30 N Gould St, Ste R Sheridan, Wyoming 82801.

14. Defendant Does 1-100 are corporate entities that acquire and/or purchase information about Medicare covered individuals sufficient to make claims to Medicare in the names of those individuals, information which Defendant Does provide to Claro and/or R&C Ent in the furtherance of the fraud described herein.

15. Defendants John and Jane Does 1-100 are the individual owners, members, officers, investors, and/or employees of Defendants that participated in the furtherance of the fraud described herein.

REGULATORY OVERVIEW

The Federal False Claims Acts

16. The FCA provides, in relevant part: [A]ny person who--

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (C) conspires to commit a violation of subparagraphs (A) or (B); and/or
- (E) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus three (3) times the amount of damages which the Government sustains because of the act of that person. 31 U.S.C.A. § 3729(a)(1).

17. The FCA permits individuals to bring a civil action in the name of the Government for violations of the respective statutes. 31 U.S.C. § 3730(b)(1).

18. The FCA defines "knowing" and "knowingly" to mean a person who, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required and an innocent mistake is not a defense to an action under these acts. *Id.*

The Anti-Kickback Statute

19. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult-to- detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. See Social Security Amendments of 1972, Pub. L.No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare- Medicaid Antifraud and Abuse

Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

20. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare and Medicaid programs.

21. Any claim filed in violation of the Anti-Kickback Statute is a false claim. 42 U.S.C. § 1320a-7a(a)(7).

22. The purchasing and selling of patient or beneficiary lists implicates the Anti-Kickback Statute, which prohibits the exchange of anything of value to induce the referral of federal healthcare program business. Purchasing patient or beneficiary lists that contain healthcare and specific patient information is prohibited under the Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(b)(4).

GOVERNMENT HEALTHCARE PROGRAMS

23. The Medicare program ("Medicare") is a health insurance program administered by the United States. It is funded by taxpayer revenue. Medicare is directed by the United States Health and Human Services Department ("HHS"). Medicare was designed to assist participating states in providing medical services and Durable Medical Equipment ("DME") to persons over sixty-five (65) years of age and certain others who qualify.

24. The Medicaid program ("Medicaid") is a health insurance program funded by state and federal taxpayer revenue. It is overseen by HHS. Medicaid was designed to

assist participating states in providing medical services, DME, and prescription drugs to qualifying financially-needy individuals.

25. CHAMPUS/TRICARE is a federally-funded program that provides medical benefits to (a) the spouses and unmarried children of (1) active duty and retired service members and (2) reservists who were ordered to active duty for thirty (30) days or longer; (b) the unmarried spouses and children of deceased service members; and (c) retirees.

Medicare and Medicaid Only Pay for Medical Services which are Reasonable, Necessary, and Performed Economically

26. Medicare only pays for services that are "medically necessary" - i.e., Medicare requires as a condition of payment that services be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(l)(A).

27. Further, providers who wish to participate in the Medicare program must ensure that their services are provided "economically and only when, and to the extent, medically necessary." 42 U.S.C. §1320c-5(a)(l).

28. The requirement of medical necessity is not met when a procedure is performed solely for profit. See U.S. ex rel. Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001) ("the requisite level of medical necessity may not be met where a party contends that a particular procedure was deleterious or performed solely for profit" (citing United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 41-42 (D. Mass. 2000) ("procedures chosen solely for defendants' economic gain are not 'medically necessary' as required by claim submission form"))).

29. Providers may be excluded from participation in the Medicare program and other federally-funded health care programs, if they routinely bill Medicare for medically unnecessary items or services. 42 CFR § 1003.102.

**Diagnostic Tests Must Be Ordered By the
Referring Physician**

30. Under the Medicare program, all diagnostic tests must be ordered by the physician who is treating the beneficiary. 42 C.F.R. § 410.32(a). Specifically, all procedures performed by a diagnostic laboratory must be ordered in writing by the physician who is treating the beneficiary. Id. § 410.33(d).

31. The Medicare Benefit Policy Manual ("MBPM") details CMS's policies for payment of Medicare benefits. MBPM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that diagnostic test be performed for a beneficiary . . . [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MBPM, Ch. 15, § 80.6.1.

32. The supervising physician for the diagnostic laboratory may not order tests to be performed by the diagnostic laboratory, unless the supervising physician is in fact the beneficiary's treating physician. 42 C.F.R. § 410.33(d). Thus the laboratory may not add any procedures based on internal protocols without a written order from the treating physician. Id.

33. Tests not ordered by the beneficiary's treating physician are considered not reasonable and necessary and, therefore, not reimbursable. Id. § 410.32(a).

ALLEGATIONS

Defendants Fraudulently Billed Government Payors for Tests that are Not Performed

34. Defendant Claro submitted claims to Government Payors for performing diagnostic genetic tests to screen for genetically inherited diseases.

35. Plaintiff/Relator Jackson's Medicare insurance had a claim made against it by Defendant Claro in January 2021 for five separate diagnostic genetic cardiac tests, with

Defendant Claro charging Relator's Medicare insurance \$5,230.00 in total for these tests.

36. The claim on Plaintiff/Relator Jackson's Medicare insurance indicates that the five genetic cardiac tests were performed on October 7, 2020, the claim was received by Medicare on January 13, 2021, and the claim was processed by Medicare on January 18, 2021.

37. Defendant Claro indicated that a saliva sample was provided to it for these genetic tests.

38. However, Plaintiff/Relator Jackson never provided a saliva sample, nor any other genetic material sample to any of the Defendants for testing.

39. Further, Relator Jackson had never heard of Claro until he saw it appear as a claim on his Medicare insurance.

40. Relator Jackson was never provided the results of these allegedly performed genetic tests.

41. Relator Jackson was never contacted by any entity or individual about the results of these allegedly performed genetic tests.

42. After Relator Jackson saw charges for these five genetic tests appear on his Medicare insurance claim summary he contacted Claro seeking information about these five genetic tests and Relator Jackson was told to call the telephone number 813-754-7777, Claro stating that this is the telephone number for Relator Jackson's treating physician that ordered the five genetic tests.

43. The telephone number 813-754-7777 is the telephone number for Defendant R&C Ent, an entity that upon information and belief is located in Florida. Relator Jackson has never provided any genetic material to Defendant R&C Ent, nor any other Defendant.

44. These five genetic cardiac tests that were billed to Relator Jackson's Medicare insurance either were not performed or were not performed on Relator Jackson's genetic material.

45. Government Payors will not pay for tests that were not performed for the insured individual.

46. Based on Relator Jackson's experience other instances of genetic tests that were not performed or were not performed on the genetic material of the government insured individual, but were billed to Government Payors will be evident upon review of Defendants' records.

Improper Use of Telephone Lead Generators

47. Under the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and Telephone Solicitation Statute, 47 C.F.R. 64.1200(12), lead generators are required to obtain leads via opt-in only.

48. In order to obtain the information necessary to submit a claim to Government Payors, Defendants and/or their hired lead generators made unsolicited telemarketing calls in violation of Federal telemarketing statutes seeking individuals insured by Government Payors.

49. The lead generators making these unsolicited telemarketing calls offered "Insurance Only" billing, with no cost to the individual if they were insured by the Government Payor for genetic tests for inheritable genetic diseases, including cardiac diseases.

50. These lead generators transmitted a false telephone number, a technique known as "caller ID spoofing", to the call recipient's caller identification, these false telephone numbers were often a number very similar to the recipients telephone number, normally with the same telephone area code and first three numbers as the recipients telephone number, a technique known as "neighbor spoofing", intended to deceive the calls recipient into believing that the caller was a local person or business, so the recipient of the call is more likely to answer the unsolicited telemarketing call.

51. The false telephone numbers transmitted by the telemarketers were not telephone numbers that the recipient could call back, a call back by a recipient resulted in hearing an error message or reaching a confused individual whose telephone number had been spoofed by the telemarketer.

52. Relator Jackson received many of the aforementioned unsolicited telemarketing calls which transmitted neighbor spoofed numbers to his cellular telephone offering him “no-cost”, insurance only billing for genetic tests to test for cardiac diseases if Relator Jackson would provide his Medicare insurance number and other identifying information. When Relator Jackson asked for identifying information from these telemarketers they would often claim to be from “The Medicare”, “Medicare Benefits” or they would terminate the call.

53. Relator Jackson, despite registering his telephone number on the Federal Do-Not-Call Registry, the Pennsylvania Do-Not-Call Registry, and repeatedly asking these telemarketers to not call him, continued to receive these harassing, intrusive, unsolicited telemarketing calls offering him free cardiac health genetic tests.

54. The funding that paid for this scheme, which, *inter alia*, resulted in unsolicited telemarketing calls, including those to Relator Jackson came from charges to Government Payors, including the charges to Relator Jackson’s Medicare, a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

55. Based on Relator Jackson’s experience, other instances of unsolicited telemarketing calls made to individuals without an opt-in, in violation Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and Telephone Solicitation Statute, 47 C.F.R. 64.1200(12), will be evident upon review of Defendants’ records.

Telehealth Fraud

56. As previously described, Relator Jackson continued to receive unsolicited telemarketing calls offering him free cardiac genetic testing, in an effort to identify the source of these calls Relator Jackson feign interest in the cardiac test in hopes of receiving identifying information about the lead generators and the entity that hired them so he could make these unsolicited telemarketing calls stop.

57. Though many unsolicited telemarketing calls of this type were received by Relator Jackson, of note were four (4) telephone calls from individuals claiming to be physicians or individuals who stated that they were not physicians but who claimed to be in contact with a physician.

58. These four (4) telephone interactions resulted in four (4) claims being submitted to Relator Jackson's Medicare Insurance "Referred by" Defendant R&C Ent, who appeared on the Medicare claim as "Rossiter & Cummaro Enterpriz, (813)754-7777" with the service claimed to be provided by "Dr. Lentsch, Kristi, M.D." on all four (4) of these claims, which correspond to calls Realtor Jackson received on:

- a) On April 3, 2020, from a telephone number that appeared on Relator Jackson's caller identification as 410-642-5153 with an individual who claimed to be with "Preventative Health Services" and a "manager" for "Dr. Javarian from Glendale, California", who asked several questions about Relator Jackson's medical history, with Relator Jackson's Medicare receiving a claim for this telemedicine call on July 28, 2020;
- b) On May 8, 2020, from a telephone number that appeared on Relator Jackson's caller identification as 814-347-2750 with an initial interaction with an individual who claimed to be with "Health and Life Networking" and asked several screening

questions which later resulted in another call from a “Private Number” with an individual who identified himself as “Dr. Hussain”, who asked several questions about Relator Jackson’s medical history with Relator Jackson’s Medicare receiving a claim for this telemedicine call on July 16, 2020;

- c) On Sept 29, 2020, from a telephone number that appeared on Relator Jackson’s caller identification as 410-401-5614 with an initial interaction that Relator Jackson describes as a “boiler room operation”, which after several screening questions resulted in him being transferred to another individual who asked him more screening questions, and him finally being transferred to an unidentified male individual who indicated that he was a doctor who asked several questions about Relator Jackson’s medical history with Relator Jackson’s Medicare receiving a claim for this telemedicine call on October 1, 2020; and
- d) On October 26, 2020 from a telephone number that appeared on Relator Jackson’s caller identification as 215-867-8956 with an initial interaction with an individual who claimed to be with “Sonoran Labs” asked several screening questions, which resulted in him being transferred to someone called a “Verifier” who asked additional screening questions, and finally Relator Jackson being transferred to an individual who identified himself as Dr. Hathaway with “My Doctors Live” who asked several questions about Relator Jackson’s medical history with Relator Jackson’s Medicare receiving a claim for this telemedicine call on November 2, 2020.

59. Each of these aforementioned telephone interactions resulted in a claim to Relator Jackson’s Medicare insurance of \$115.00 by Defendant R&C Ent, for a total amount billed of \$460.00 for these duplicate medical services.

60. Despite Relator Jackson's Medicare insurance claiming that the "Service Provided" was by Dr. Kristi Lentsch, M.D., Relator Jackson is unaware of ever having interacted with Dr. Lentsch.

61. These four (4) aforementioned telephone calls were the result of unsolicited telemarketing calls made to Relator Jackson.

62. These four (4) telephone calls, were all for the same duplicate medical service, screening for approval of genetic cardiac health testing.

63. Though the four (4) aforementioned telephone calls involved questions about Relator Jackson's cardiac history, Relator Jackson never submitted any genetic material for testing, Relator Jackson's only answered questions over the telephone.

64. Despite Relator Jackson never submitting any genetic material for testing, Defendants used the Medicare insurance information it obtained during these unsolicited telemarketing calls to submit a fraudulent claim to Relator Jackson's Medicare insurance for a genetic test that was not performed on Relator Jackson.

65. Based on Relator Jackson's experience, other instances of unsolicited telemarketing calls made to individuals without an opt-in, in violation Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, will be evident upon review of Defendants' records.

Notice of Telemarketing Violations to Defendant and Continued Violations

66. Relator Jackson's counsel was able to identify Defendant R&C Ent as a potential source of some of the unsolicited telemarketing calls being made to Relator Jackson from a mailing it sent to Relator Jackson after one of the aforementioned unsolicited telemarketing calls. This mailing arriving around April, 2020.

67. Relator Jackson's counsel sent Defendant R&C Ent notice of its telemarketing violations on June 2, 2020. This is over a month before Defendant R&C Ent

made a claim to Relator Jackson's Medicare insurance, the first claim occurring on July 16, 2020.

68. Despite this notice, Defendant R&C Ent continued to make at least two more unsolicited telemarketing calls to Relator Jackson, and subsequently bill his Medicare insurance four (4) separate times for telemedicine calls, all for same duplicate medical service, screening for approval of genetic cardiac health testing.

COUNT I

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

69. Relator incorporates paragraphs 1-68 of this Complaint, as though fully set forth herein. This count sets forth claims for treble damages and civil penalties under the FCA.

70. As described in greater detail above, Defendants abused Government healthcare programs in connection with fraudulent billing to Government Payors for medical testing that was not performed, as well as engaging in fraudulent marketing practices, and improper practices involving telehealth physicians.

71. Under the FCA, Defendants have violated:

- i. 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- ii. 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.
- iii. 31 U.S.C. § 3729(a)(1)(C) by conspiring to commit a violation of 31 U.S.C. § 3729(a)(1)(A) and/or (a)(1)(B); and

iv. 31 U.S.C. § 3729(a)(1)(G) by knowingly making, using, or causing to be made or used a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government.

72. Because of the false claims made by Defendants, the United States has suffered and continues to suffer damages, and is therefore entitled to a recovery as provided by the FCA of an amount to be determined at trial, plus a civil penalty for each violation.

COUNT II

VIOLATIONS OF THE ANTI-KICKBACK STATUTE

73. Relators incorporate paragraphs 1-72 of this Complaint as though fully set forth herein.

74. The Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving anything of value to induce rewards, referrals or general federal healthcare business. 42 U.S.C. § 1320a-7b(b).

75. As described in the Complaint, Defendants knowingly and intentionally paid lead generators financial compensation in exchange for improper beneficiary leads and/or their Government Payor insurance information.

76. Defendants' actions caused Government Payors to reimburse them for items stemming from claims that resulted from prohibited activities under the Anti-Kickback Statute.

PRAYER

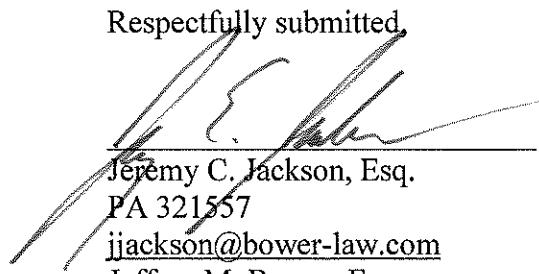
WHEREFORE, Relator, on behalf of the United States, respectfully requests that:

- a. This Court enter an order determining that Defendants violated the FCA by making false statements and records to cause false claims to be submitted to the United States;
- b. This Court enter an order requiring Defendants to pay treble damages and the maximum civil penalties allowable to be imposed for each false or fraudulent claim presented to the United States;
- c. This Court enter an order requiring that Defendants cease and desist from violating the FCA ;
- d. This Court enter an order requiring Defendants to pay all expenses and attorney's fees and costs associated with this action;
- e. This Court enter an order paying Relator the maximum statutory award for his contributions to the prosecution of this action; and
- f. Any and all other relief the Court determines to be reasonable and just.

PLAINTIFF/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS.

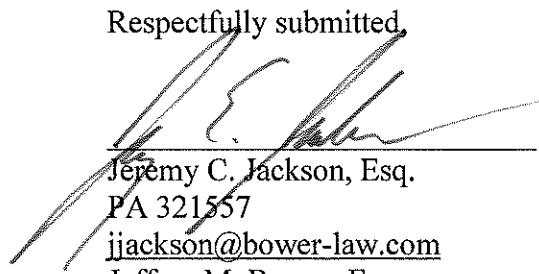
Dated: March 19, 2021

Respectfully submitted,


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Counsel for Relator

CERTIFICATE OF SERVICE

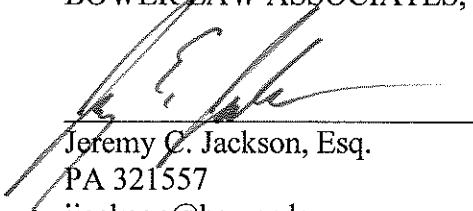
I hereby certify that, in accordance with F.R. Civ. P. 4(i) and the requirements of 32 U.S. Code 3730(b)(2), on this 19th day of March 2021, I mailed, via Certified United States Mail, a copy of the foregoing Complaint, to the following:

Attorney General of The United States
U.S. Department of Justice
Civil Division
950 Pennsylvania Avenue, N.W.
Washington, DC 20530-0001

And hand-delivered same to the following:

United States Attorney for the Middle District of Pennsylvania
Attn: Civil Frauds/False Claims
Herman T. Schneebeli Federal Building
240 West Third Street
Williamsport, PA 17701-6465

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